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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,109	PEREZ GOMARIZ ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/22/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/446,352* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission of RCE and the amendment filed on November 22, 2004 have been entered. The claims pending in this application are claims 1 and 7. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on November 22, 2004.

Specification

2. The amendment filed on March 22, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The newly added SEQ ID Nos: 4 and 5 and Figures 11 and 12 (containing SEQ ID Nos: 4 and 5) are not supported by the original disclosure since the references recited VPAC1-specific agonist and VPAC2-specific agonist (containing SEQ ID Nos: 4 and 5) in the specification, page 20, first paragraph are not originally incorporated by reference.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To the extent that the claimed composition/or methods are not described in the instant disclosure, claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

There is a phrase "a pharmaceutically and therapeutically effective formulation having a unit dosage of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist in milligrams per kilogram of body weight" in newly added independent claim 7. Although the specification describes that a daily dosage of active ingredient can be about 0.01 to 100 milligram (mg) per kilogram of body weight (see the specification, page 15, last paragraph bridging to page 16, first paragraph), the specification fails to define or provide any disclosure to support any milligrams per kilogram of body weight as recited in claim 7.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION

REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." (emphasis added).

5. Claims 1 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of certain vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonists for the prevention of septic shock induced by LPS in certain animal, does not reasonably provide enablement for using a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of any vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist for the treatment and/or prevention of any kind of septic shock in any kind of animal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance to use a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of any vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonists for the treatment and/or prevention of septic shock induced by LPS in any kind of animal. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability whether a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of any vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist recited in claims 1 and 7 can be used for the treatment and/or prevention of any kind of septic shock in any kind of animal.

Claim 1 is directly to a pharmaceutical composition for the treatment and/or prevention of septic shock, comprising an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist with a pharmaceutically acceptable carrier. Claim 7 is directed to a pharmaceutical composition for the treatment and/or prevention of septic shock, comprising a pharmaceutically and therapeutically effective formulation having a unit dosage of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist in milligrams per kilogram of body weight with a pharmaceutically acceptable carrier. Thus claims 1 and 7 are drawn to a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of any vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist for the treatment and/or prevention of any kind of septic shock in any kind of animal. The specification only describes that two vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonists, [K 15, R 16, L 27]VIP [1-7]-GRF[8-27] and Ro 25-1553 Ac-[Glu 8, Lys 12,

Nle 17, Ala 19, Asp 25, Leu 26, Lys 27,28, Gly 29,30,Thr 31)-VIP cyclo[21-25] (the specification does not provide their whole sequences) can be used for protecting against the lethal effects of LPS-induced septic shock in BALB/c mice. However, the specification does not provide a guidance to show that a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of any vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist recited in claims 1 and 7 can be used for the treatment and/or prevention of any kind of septic shock in any kind of animal. Since although it is known that Gram-positive bacteria uses a Toll-like receptor distinct from that used by the LPS, Gram-positive bacteria infection also causes septic shock (see page 2, sixth paragraph in attachment for septic shock). Thus, besides LPS, septic shock can be caused other factors. However, note that claims 1 and 7 are not limited to LPS-induced septic shock.

With these above unpredictable factors, the skilled artisan will have no way to predict the experimental results. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. The undue experimentation at least includes to test whether a pharmaceutical composition comprising an effective pharmaceutical unit dosage formulation of any vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist recited in claims 1 and 7 can be used for the treatment and/or prevention of any kind of septic shock in any kind of animal.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fishbein *et al.*, (Peptides, 15, 95-100, 1994).

Fishbein *et al.*, teach a chimeric VIP-PACAP analogue but not VIP pseudopeptides function as VIP receptor antagonists. Since pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP are agonists of VIP receptor with different binding affinities (see abstract in page 95 and Table in page 98) and it is known that VPAC1 receptor is one of VIP receptors (see the specification, page 7, third paragraph), pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP taught by Fishbein *et al.*, are VPAC1 receptor agonists as recited in claim 1. According to the definition of pharmaceutically acceptable carrier (see page 14, second paragraph), serum albumin is one of pharmaceutically acceptable carriers. Since Fishbein *et al.*, teach that the incubation buffer used for pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP (ie., VPAC1 receptor agonists) includes 0.2% BSA (see page 96, left column, fourth paragraph), BSA is considered as a pharmaceutically acceptable carrier recited in claim 1. Thus one or more above pseudopeptides and BSA taught by Fishbein *et al.*, are components of a pharmaceutical composition as recited in claim 1. Since Fishbein *et al.*, teach that one of VPAC1 receptor agonists, [ψ3-4]VIP, binds to VPAC1 receptor with an affinity of 0.2 μM (see page 95, abstract), Fishbein *et al.*, disclose an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist (i.e., 0.2 μM

[ψ3-4]VIP in binding studies) with a pharmaceutical composition (ie., BSA) as recited in claim 1. Although Fishbein *et al.*, do not show that the pharmaceutical composition comprising 0.2 μM [ψ3-4]VIP and 0.2% BSA can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Response to Arguments

In page 4, third paragraph bridging to page 5, third paragraph of applicant's remarks, applicant argues that "[F]ishbein fails to teach a pharmaceutical composition comprising 'an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist.' In fact, Fishbein fails to teach or suggest any pharmaceutical formulation at all".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. Since Fishbein *et al.*, teach that the incubation buffer used for pseudopeptides [ψ2-3]VIP, [ψ3-4]VIP, [ψ4-5]VIP, [ψ5-6]VIP, [ψ6-7]VIP, and [ψ8-9]VIP (ie., VPAC1 receptor agonists) includes 0.2% BSA (see page 96, left column, fourth paragraph), BSA is considered as a pharmaceutically acceptable carrier recited in claim 1. Thus one or more above pseudopeptides and BSA taught by Fishbein *et al.*, are components of a pharmaceutical composition as recited in

claim 1. Since Fishbein *et al.*, teach that one of VPAC1 receptor agonists, [ψ3-4]VIP, binds to VPAC1 receptor with an affinity of 0.2 μM (see page 95, abstract), Fishbein *et al.*, disclose an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist (i.e., 0.2 μM [ψ3-4]VIP in binding studies) with a pharmaceutical composition (ie., BSA) as recited in claim 1. Although Fishbein *et al.*, do not show that the pharmaceutical composition comprising 0.2 μM [ψ3-4]VIP and 0.2% BSA can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey* , 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

8. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Gourlet *et al.*, (Peptide, 18, 1539-1545, December 1997).

Gourlet *et al.*, teach development of high affinity selective VIP1 receptor agonists. Since two VIP receptor agonists, [R16]chicken secretin and [K15, R16, L27]VIP(1-7)/GRF(8-27), have much stronger affinity for VIP1 receptor than VIP 2 receptor (see abstract in page 1539 and right column in page 1544) and it is known that VIP1 receptor and VPAC 1 are identical, [R16]chicken secretin and [K15, R16, L27]VIP(1-7)/GRF(8-27) taught by Gourlet *et al.*, are two

VPAC 1 agonists. According to the definition of pharmaceutically acceptable carrier (see page 14, second paragraph), serum albumin is one of pharmaceutically acceptable carriers. Since Gourlet *et al.*, teach that the buffer used for the binding assay includes 1% bovine serum albumin (BSA) (see page 1541, left column, fifth paragraph), BSA is considered as a pharmaceutically acceptable carrier. Thus [R16]chicken secretin or/ and [K15, R16, L27]VIP(1-7)/GRF(8-27), and BSA are components of a pharmaceutical composition as recited in claim 1. Since Gourlet *et al.*, teach that [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) binds to VIP1 receptor with IC_{50} of 1 nM (see page 1539, abstract), Gourlet *et al.*, disclose an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist (i.e., 1 nM [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) in binding studies) with a pharmaceutical composition (ie., BSA) as recited in claim 1. Although Gourlet *et al.*, do not show that the pharmaceutical composition comprising [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) in the binding buffer can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Response to Arguments

In page 5, last paragraph bridging to page 6, first paragraph of applicant's remarks, applicant argues that "like in Fishbein, the VPAC1 agonists are only used in the study of binding properties for example, and is not provided in an effective pharmaceutical unit dosage formulation for pharmaceutical or therapeutic administration. Therefore. Gourlet fails to teach or suggest the recited unit dosage formulation".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. According to the definition of pharmaceutically acceptable carrier (see page 14, second paragraph), serum albumin is one of pharmaceutically acceptable carriers. Since Gourlet *et al.*, teach that the buffer used for the binding assay includes 1% bovine serum albumin (BSA) (see page 1541, left column, fifth paragraph), BSA is considered as a pharmaceutically acceptable carrier. Thus [R16]chicken secretin or/ and [K15, R16, L27]VIP(1-7)/GRF(8-27), and BSA are components of a pharmaceutical composition as recited in claim 1. Since Gourlet *et al.*, teach that [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) binds to VIP1 receptor with IC_{50} of 1 nM (see page 1539, abstract), Gourlet *et al.*, disclose an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist (i.e., 1 nM [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) in binding studies) with a pharmaceutical composition (ie., BSA) as recited in claim 1. Although Gourlet *et al.*, do not show that the pharmaceutical composition comprising [R16]chicken secretin or [K15, R16, L27]VIP(1-7)/GRF(8-27) in the binding buffer can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic

shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Pickett Seltner *et al.*, (Vision Research, 35, 1265-1270, 1995).

Pickett Seltner *et al.*, teach the effect of vasoactive intestinal peptide on development of form deprivation myopia (FDM) in the chick. Since Pickett Seltner *et al.*, teach that two VIP antagonists, one is selective for central nervous system VIP receptors and another is selective for peripheral nervous system VIP receptors, are injected into chicks with saline and completely abolish FDM (see page 1265, abstract, page 1266, third paragraph, page 1267 and Figure 3), two VIP antagonists taught by Pickett Seltner *et al.*, are two VIP receptor agonists. According to the definition of pharmaceutically acceptable carrier (see page 14, second paragraph), saline is one of pharmaceutically acceptable carriers. Since Pickett Seltner *et al.*, teach to inject two VIP antagonists with concentrations of 2×10^{-10} and 2×10^{-8} mol respectively into chicks with saline (see page 1267 and Figure 3), Pickett Seltner *et al.*, disclose an effective pharmaceutical unit dosage formulation of vasoactive intestinal peptide/pituitary adenylate cyclase-activating peptide receptor agonist (i.e., 2×10^{-10} or 2×10^{-8} mol) with a pharmaceutical composition (ie., saline) as recited in claim 1. Although Pickett Seltner *et al.*, do not show that the pharmaceutical

composition comprising a CNS VIP antagonist or a PNS VIP antagonist can used for the treatment and/or prevention of septic shock as recited in claim 1, the effect of the pharmaceutical composition recited in claim 1 in the treatment and/or prevention of septic shock is considered as an intended use of the pharmaceutical composition recited in claim 1. It is known that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto* , 136 USPQ 458, 459 (CCPA 1963).

Conclusion

10. No claim is allowed.

11. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is 571-272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (571) 272-0745.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
December 27, 2004

FRANK LU
PATENT EXAMINER